

ESTTA Tracking number: **ESTTA470984**

Filing date: **05/04/2012**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91200436
Party	Defendant Medinol Ltd.
Correspondence Address	JOHN P HALSKI CADWALADER WICKERSHAM & TAFT LLP ONE WORLD FINANCIAL CENTER, 20TH FLOOR NEW YORK, NY 10281 UNITED STATES john.halski@cwt.com, docketing@cwt.com, jennifer.chick@cwt.com, dorothy.auth@cwt.com
Submission	Other Motions/Papers
Filer's Name	John P. Halski
Filer's e-mail	john.halski@cwt.com, docketing@cwt.com, jennifer.chick@cwt.com, dorothy.auth@cwt.com
Signature	/JOHN P. HALSKI/
Date	05/04/2012
Attachments	91200436_Warren_Sherman_Expert_Report_5-4-12.pdf ( 33 pages )(1201741 bytes )

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE  
TRADEMARK TRIAL AND APPEAL BOARD

CARDIOMEMS, INC.,

Opposer,

v.

MEDINOL LTD.,

Applicant.

In re Serial No. 85/082098

Mark: CHAMPIONIR

Opposition No. 91200436

**EXPERT REPORT OF WARREN SHERMAN, M.D.**

I, Warren Sherman, declare as follows:

This statement constitutes a summary of my expected opinion testimony regarding the absence of any likely confusion between the CHAMPIONIR mark owned by Applicant Medinol Ltd. (“Medinol”) and the CHAMPION mark (“Opposer’s Mark”) owned by Opposer CardioMEMS, Inc. (“Opposer”).

**I. BACKGROUND AND QUALIFICATIONS**

1. I am a senior Interventional Cardiologist and Director, Stem Cell Research and Regenerative Medicine at the Center for Interventional Vascular Therapy of Columbia University Medical Center. I have held this position since 2005.
2. From 2001 to 2005, I was Associate Director of the Cardiac Catheterization Laboratory at Mount Sinai Hospital in New York, Director of the Center for Cell Therapy, and an Assistant Professor in the Mount Sinai School of Medicine.
3. I was at Beth Israel Medical Center (New York) from 1989-2001. While I was there, I was Director of the Cardiac Catheterization Laboratories, and, for the last five of those years, Director of the Division of Invasive and Interventional Cardiology.
4. I am board certified (American Board of Internal Medicine) in internal medicine, cardiovascular diseases and interventional cardiology.
5. During the last twenty years, I have personally performed more than 4,000 percutaneous coronary interventions. Since 1996, over 80% of those have involved the placement of stents. At Columbia University Medical Center there are eleven cardiologists on staff, performing more than 3,000 interventions per year. Our program typically treats a high risk population of patients who have complex coronary disease, i.e., chronic total occlusions and diseased bypass grafts. In my position, I advise patients with very

advanced coronary disease and the physicians who are taking care of them. Many of the patients I treat have been turned down by other practices.

6. I currently implant an average of 100 stents per year, mainly drug-coated stents. However, I also implant bare metal stents when the patient's condition so requires. For example, bare metal stents may be preferred if a patient has drug or polymer intolerances, low risk of restenosis, a short lesion in a large vessel, small vessel lesions (drug-eluting stents are only available in lengths greater than 2.5 mm) or when planned surgical procedure requires that antiplatelet medications be held.
7. I have been a teacher and researcher in the field of cardiology for over twenty years, with academic appointments at Oregon Health Sciences University, Albert Einstein College of Medicine in New York, and Mount Sinai School of Medicine in New York. I am currently an Associate Professor of Clinical Medicine at Columbia University. I have won two awards for outstanding teaching.
8. In addition to performing interventional cardiology procedures and teaching, I also conduct research on various issues within the field of cardiology. Presently, I am evaluating the potential of stem cells to improve the function of the heart. My interest in this particular field arose from the frustrations experienced in treating patients who have reached the absolute limits of interventional, surgical and medical therapies. For those patients, no further angioplasty or stenting is possible. I have participated in a number of clinical trials relating to coronary stents, adjunctive and support devices for coronary interventions, and investigational devices for coronary and myocardial stem cell injections.

9. Of particular relevance to these proceedings, I am familiar with the sensor device that CardioMEMS is apparently trying to develop. In fact, between 2008 and 2009, I participated in the Opposer's CHAMPION (CardioMEMS Hearth Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Patients) clinical trial (hereinafter, "the Champion Trial"). My involvement consisted of assisting the primary operator in several implantations.
10. For further details of my experiences in the vascular field, I have attached my resume as Exhibit A. It includes my employment history, education, post-doctoral training, honors, professional memberships, publications, research support and grants.
11. I have previously consulted for Medinol in connection with litigation involving stents made by Guidant Corporation. I served as an expert in Medinol, Ltd. v. Guidant Corp., Civ. No. 03-civ-2604 (S.D.N.Y.), in which I testified at trial at the request of Medinol regarding the validity of some of Medinol's patents. I also gave a deposition in that case on issues of infringement and validity.

## **II. MATERIALS CONSIDERED**

12. In preparing my statement, I considered the trademark registration for Opposer's mark, the file history for the application underlying the CHAMPIONIR mark, the pleadings in this matter and the materials identified as Exhibits B and C attached hereto. In addition, I have drawn upon my personal experience as a physician and a researcher, and the general knowledge of those in the field of coronary and peripheral artery disease.

### **III. SUMMARY OF OPINIONS**

13. This statement provides my expected opinion testimony on the issues of whether there might be any likelihood of confusion between Medinol's CHAMPIONIR Mark and the Opposer's Mark.
14. In summary, it is my opinion that there will be no likelihood of confusion between these marks because, among other considerations, (i) the respective customers for the products of Medinol and of Opposer are highly sophisticated individuals who will readily recognize and instinctively know that the different products originate with different sources; (ii) the goods identified in the underlying applications for each mark are significantly different from each other; (iii) the respective channels of trade for such goods are significantly different from each other; and (iv) whereas the CHAMPIONIR mark inherently calls to mind the highly successful and well-known NIR stents which are closely associated with Medinol, the CHAMPION mark is non-distinctive and highly unlikely to trigger any association. Each of these bases is discussed in detail herein below.
15. At the outset and to set my opinion in proper context, and as I explain in more detail below, the intended customers of Medinol's CHAMPIONIR peripheral stents and the intended customers of Opposer's heart failure sensors are groups of highly sophisticated individuals who will readily recognize the different sources of the parties' respective products despite any overlap of the root word "champion" in their respective marks. Specifically, peripheral stents are used in vessels in the periphery of the body, i.e. away from the heart. Medinol's intended customers typically are vascular interventionalists who treat patients having, e.g. peripheral artery disease (PAD), whereas Opposer's intended customers typically would be physicians who specialize in end-stage heart

disease patients. The level of sophistication for both groups of medical professionals support the position that there is a low likelihood that any of these sophisticated customers will confuse a CHAMPIONIR-designated product with a CHAMPION-designated product.

16. Moreover and particularly in view of the general sophistication of the intended customers, the products that Medinol intends to sell under the CHAMPIONIR Mark, namely peripheral stents, which are by definition implanted in the peripheral vessels of the body (i.e., away from the heart, such as in the leg). Peripheral stents are significantly different from either the goods identified by the Opposer in the underlying application for Opposer's Mark or the "heart failure sensor" devices specifically identified by the Opposer in this Opposition. As such, these customers are unlikely to confuse the CHAMPIONIR mark directed to peripheral stents with Opposer's mark directed to the heart failure sensors alleged to be offered by the Opposer. Given the very different purposes the parties' respective devices serve and the critical, but different, roles they may serve in monitoring (Opposer) and treatment (Medinol) of vascular disease, those who would employ them will be very cognizant of the different sources.
17. Likewise, there are distinct channels of commerce for the products offered by the respective parties, such that a sophisticated customer will readily distinguish between products using the CHAMPIONIR mark in connection with the sale of peripheral stents from products using Opposer's mark in connection with heart failure sensors.
18. In addition, the sophisticated customers for these products will recognize the CHAMPIONIR mark as related to the revolutionary, highly successful and well-known NIR mark as a source indicator of Medinol products. The obvious correlation between the NIR and CHAMPIONIR marks, particularly since these are used in connection with stents, diminishes any possibility

of confusion with regard to the source of goods offered for sale under Medinol's CHAMPIONIR mark.

19. By direct contrast, the Opposer's Mark – CHAMPION – lacks any inherent distinctiveness considered by itself. The word "champion" is primarily a laudatory adjective used widely on any number of products, and as such it is unlikely to trigger any associations between the products newly offered by the Opposer under the Opposer's Mark and any particular source, including either Medinol or CardioMEMS.

#### **IV. SOPHISTICATION OF INTENDED CUSTOMERS**

20. Broadly, customers for the products at issue in this matter tend to be highly experienced and sophisticated medical professionals in such facilities as hospitals having laboratories dedicated to diagnosis, treatment and/or monitoring of cardiac or vascular issues. The product purchasers would readily differentiate between the very different products in that Medinol's peripheral stents will be sold to specialists in the field of peripheral artery disease while the Opposer's products may be sold, for example, to cardiologists who specialize in chronic heart failure.
21. Medical professionals acting as customers for one set of products or the other are highly sophisticated and are very sensitive with regard to the source of the goods they use with their patients for obvious reasons. Typically, customers for peripheral stents are medical doctors with a specialty in the treatment of peripheral artery disease and/or particular training in vascular intervention as a means for delivering stent devices. Through professional journals, publications and seminars, medical professionals in the fields described above will keep themselves informed of new developments with regard to the products at issue in this matter. For example, specialists in the field of peripheral artery



disease will certainly be aware of Medinol's stents, including specifically the NIR stent, based on the positive attention these products have received in various published studies and articles. See, e.g., D.S. Baim, M.D., et al., [Final results of a randomized trial comparing the NIR stent to the Palmaz-Schatz stent for narrowings in native coronary arteries](#), Am J. Cardiol 87:152-6 (2001).

22. Likewise, specialists in the field of late-stage heart failure, such as those likely to be involved in the purchase of the type of heart failure sensors alleged to be offered by the Opposer may be aware of the Champion Trials but, have very little, if any, familiarity with peripheral artery disease and interventional therapies therefor. This would be especially so in view of the history, development and current applications of stents in interventional treatments, including as it pertains to the Medinol NIR family of stents.
23. Based solely on the sophistication of the intended customers for the respective products of the parties, it is my opinion that there is virtually no likelihood of confusion between the CHAMPIONIR Mark to be used by Medinol and Opposer's Mark.

## **V. GOODS OFFERED BY THE PARTIES**

24. As noted, Medinol intends to use the CHAMPIONIR Mark in connection with the sale of peripheral stents, whereas the Opposer applied for registration of the CHAMPION mark based on the following goods and services:

Class 10: Medical diagnostic sensors for measuring properties of the body, namely, pressure, corresponding catheter-based delivery apparatus to deliver sensors to locations within the body; telemetry devices for medical application and software to interrogate, receive, process and display pressure data or derived quantities for viewing and printing sold as a unit.

Class 44: Providing a web site that enables users to upload and access health and medical data.

The Opposer alleges that it is using the Opposer's Mark specifically with "heart failure sensors" (that is, those used in the Champion Trial).

25. Medinol's products and Opposer's products are different. Whether identified as the goods set forth under Class 10 above or simply as "heart failure sensors", the goods purported to be used in connection with Opposer's Mark have no significant functional similarities with peripheral stents. Rather, the Opposer's device is intended for use in monitoring physiological parameters of the heart, and, as such only provides data to a cardiac output for use by heart failure physicians. Once implanted, it imparts no direct therapeutic effect on the anatomic structure(s) with which it comes in contact. Medinol's peripheral stents, on the other hand, are designed for treating patients and restoring the normal function of diseased arteries, and, in doing so, reversing the consequences of specific patient illnesses.
26. A heart failure sensor functions by receiving a pressure signal and transmitting it to an external receiver. This results in data which provides real-time measurements of the function of a patient's heart. In contrast, a peripheral stent is a mechanical scaffold that is positioned and expanded in a peripheral artery (e.g. in the leg) to push open and maintain it in a functionally open state. Thus, these are significantly different devices with different functional properties.
27. Given the significant differences between these products, customers are highly unlikely to confuse the respective marks used in connection with these goods, regardless of how similar or dissimilar the marks when considered in a vacuum.

## **VI. CHANNELS OF TRADE**

28. The typical channels of trade used by companies such as the parties in this matter differ significantly between those for stents, on the one hand, and heart failure sensors, on the other.
29. Peripheral stents are sold for use by vascular interventionalists, who specialize in implanting stents for the purpose of maintaining peripheral vessels in an open and functioning position. By contrast, heart failure sensors are sold for use by doctors who specialize in late-stage heart disease patients.

## **VII. WIDESPREAD RECOGNITION OF THE CHAMPIONIR MARK**

30. The superficial similarity of the CHAMPIONIR Mark and Opposer's Mark (because of the common term "champion") must be viewed in light of the popularity of the well-known NIR brand, particularly because Medinol's marks are used only in connection with stents, as compared to the ubiquity and non-distinctiveness of "Champion" by itself.
31. The CHAMPIONIR Mark deliberately invokes the popular NIR brand and constitutes the dominant element of this mark. Insofar as the mark will be used in connection with stents, the typical customer as described above will naturally associate the "nir" syllable with the highly successful NIR stent – a widely known and highly regarded product in this field.
32. The NIR stent has enjoyed considerable commercial success since its introduction into the market. A brief review of the sales figures for the NIR stent clearly substantiate the widespread recognition of the NIR mark in general, and its popularity amongst the sophisticated customers of stents in particular. Since 1996, Medinol sold over two million NIR stents for distribution. On the strength of vascular interventionalists – myself included – making NIR their first choice for stents. In the first nine months of 1999, a mere three years after its initial release, NIR stent sales reached about \$461 million in

worldwide (see Exhibit B (Boston Scientific Corporation, Form 10-Q, dated November 15, 1999) at 20 and 21).

33. The NIR product line also includes products such as the NIR ON™ Ranger™, NIR® Primo™, NIR® w/SOX™ and NIROYAL™. Each of these products was successful in the market (see, e.g., Exhibit C (Boston Scientific Corporation, Form 10-K, dated March 30, 2000) at 10). and strengthened the dominant association between Medinol products and the term “NIR.”
34. Medinol continues to build a line of products around the success of the NIR mark, as further evidenced by the series of NIR-related marks for which Medinol has applied in recent years – e.g. NIRSIDE (App. Serial No. 77822653), NIRTINOL (App. Serial No. 77700534), PIONIR (App. Serial No. 77233796), NIRROR (App. Serial No. 85441788). The cumulative effect of these marks further evidences the strong association between the CHAMPIONIR mark and Medinol as the source of such NIR-branded products.
35. Thus, before any consideration of Opposer’s Mark for sake of comparison, the CHAMPIONIR Mark benefits from the strength of the NIR brand developed over a decade of commercial success and professional acceptance of Medinol’s products. On that basis alone, the sophisticated medical professionals in the market for stents will immediately recognize the CHAMPIONIR Mark as a Medinol product.

#### **VIII. NON-DISTINCTIVE NATURE OF THE OPPOSER’S MARK**

36. By contrast, “Champion” as a stand-alone mark implies no such brand connotation. As a laudatory term meaning “victor” (among other superlative synonyms), the word is a popular mark for a wide range of products. The following are just a handful of examples that I could find in a simple online search of registered trademarks:

- U.S. Trademark Registration No. 85502410, CHAMPION, used in connection with “custom construction of residential and commercial structures, namely, modular, manufactured, mobile and commercial buildings”;
- U.S. Trademark Registration No. 85558235, CHAMPION, used in connection with “medical tape”;
- U.S. Trademark Registration No. 85082591, CHAMPION, used in connection with “earth moving machines, namely, motor graders”;
- U.S. Trademark Registration No. 78883895, CHAMPION, used in connection with “comic books”;
- U.S. Trademark Registration No. 78616070, CHAMPION, used in connection with “mops”;
- U.S. Trademark Registration No. 78674823, CHAMPION, used in connection with “financial services, namely, student loan management and servicing”; and
- U.S. Trademark Registration No. 78555982, CHAMPION, used in connection with “dental floss.”

Likewise, an internet search of the term “champion” turns up hits as disparate as sportswear (<http://www.championusa.com/>), replacement windows

(<http://www.championwindow.com/>), stamp collecting (<http://www.championstamp.com/>)

and spark plugs (<http://www.championsparkplugs.com/>). It does not stretch the imagination to assume that nearly any line of products has at least one company – if not multiple – offering their goods with the boast that their goods are the “champion” in that field.

37. In fact, a “Champion stent” unrelated to either party was at one time in development by Guidant until that company decided to forego the project in favor of the “Xience stent.” See Shelley Wood, Next-Generation Drug-Eluting Stents Tackle Shortcomings of Cypher, Taxus, HeartWire, February 7, 2006, <http://www.theheart.org/article/641591> (retrieved April 30, 2012). Clearly, “champion” is a popular designation across industries, and unsurprisingly so given the ordinary meaning of the word. See, e.g., Joseph G. Salloum, M.D., et al. Carotid

Artery Repair: Stent Or Scalpel?, The Doctor Will See You Now, March 1, 2002, <http://www.thedoctorwillseeyounow.com/content/heart/art2026.html> (retrieved April 30, 2002) (“Sometimes, the progress of a new medical technique is a little like the rise of a new boxing champion. ... Before a newcomer can be accepted, the reigning champion must be clearly and decisively defeated.”) (emphasis added).

38. As such, whereas the sophisticated medical professional customer likely will recognize that CHAMPIONIR is a derivation of the established brand NIR (and thus attribute the same goodwill that the NIR brand has developed to the related goods to be offered under the CHAMPIONIR mark), these same customers likely will not attribute any particular significance to the otherwise commonplace and laudatory term “champion” featured by itself on a heart failure sensor as proposed by Opposer.
39. As a result, any supposed distinctiveness of the Opposer’s Mark will stem directly from the Champion Trials.<sup>1</sup> Such medical professionals are unlikely to extend any association between Opposer’s Mark and the Opposer to stents, let alone any product bearing the CHAMPIONIR Mark (particularly in view of the strong association otherwise present between the CHAMPIONIR Mark and other NIR-branded products).

## **IX. COMPENSATION**

40. My compensation rate is \$650 per hour.

---

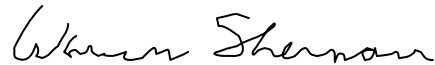
1. The CHAMPION mark originates from an acronym based on the full name of the trial, i.e. CardioMEMS Hearth Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Patients.

**X. SUPPLEMENTATION**

41. I may supplement this report if I become aware of additional pertinent information or in response to the testimony or reports of others, or provide additional expert opinion in response to the statements of other witnesses, including witnesses who testify on behalf of Medinol.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: May 4, 2012

---

# **EXHIBIT A**



NAME Sherman, Warren	POSITION TITLE Associate Professor, Medicine		
eRA COMMONS USER NAME (credential, e.g., agency login) WS2157			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	MM/YY	FIELD OF STUDY
Massachusetts Institute of Technology	B.S.	06/73	Life Sciences
SUNY Upstate Medical Center, Syracuse, NY	M.D.	06/77	Medicine
University of Rochester, NY	Postdoctoral	06/80	Internal Medicine
Oregon Health Science University (OHSU)	Postdoctoral	06/81	Cardiovascular Disease

## A. Personal Statement

## B. Positions and Honors

### Positions and Employment

1977-1980	Intern / Resident, Internal Medicine, Rochester General Hospital, Rochester, NY
1980-1982	Fellow, Cardiovascular Disease, University and Veteran's Hospitals, OHSU, Portland, OR
1982-1983	Assistant Professor, Department of Medicine, OHSU, Portland, OR
1983-1986	Instructor, Department of Medicine, Mount Sinai School of Medicine, New York, NY
1984-1985	Director, Cardiac Catheterization Laboratory, Elmhurst Hospital, New York, NY
1986-1994	Assistant Professor, Department of Medicine, Mount Sinai School of Medicine, New York, NY
1987-1989	Director, Coronary Care Unit, Mount Sinai Hospital, New York, NY
1989-2001	Director, Cardiac Catheterization Laboratory / Director, Division of Cardiovascular Interventions, Beth Medical Center, New York, NY
1994-2001	Assistant Professor, Department of Medicine, Albert Einstein College of Medicine, New York, NY
2001-2005	Assistant Professor, Department of Medicine, Mount Sinai School of Medicine, New York, NY
2001-2005	Director, Center for Cell Therapy / Director of Education / Associate Director, Cardiac Catheterization Laboratory, Mount Sinai Hospital, New York, NY
2005-	Associate Professor, Department of Medicine, Columbia University Medical Center, New York, NY
2005-	Director, Stem Cell Research and Regenerative Medicine, Center for Interventional Vascular Therapy, Skirball Center for Cardiovascular Diseases, Columbia University Medical Center, NY, NY

### Other Experience and Professional Memberships

1983	Fellow, American College of Cardiology
1990-1994	Committee on Scientific Affairs (Institutional Review Board), Beth Israel Medical Center, NY, NY
2004-present	Editorial Board, Cytotherapy
2006-present	Editorial Board, Cell Transplantation
2004-present	Director, Annual International Conference on Cell Therapy for Cardiovascular Diseases, New York, NY; Sponsors: Cardiovascular Research Foundation and Columbia University Medical Center
2006-2007	Member, Data and Safety Monitoring Board, Safety and Efficacy of Autologous, Intracoronary stem Cell Injections in Total Coronary Occlusion. Sponsor: Arteriocyte, Inc. and NIH/4R42HL080856-02
2007	NIH Study Section ZRG1 CVS-K (10) B
2008	NIH Study Section ZRG1 CVS-K 02 M
2008	NIH Study Section ZRG1 CVS-K (10), Secondary Reviewer
2008	Reviewer, Selection Committee, applications for AHA-Jon DeHaan Myogenesis Center

- 2008-present Chair, Data and Safety Monitoring Board. Intramyocardial Delivery of Autologous Bone Marrow Cells in Patients with Heart Failure Due to Dilated Cardiomyopathy. Sponsor: Aastrom Biosciences, Inc.
- 2009-present Chair, Data and Safety Monitoring Board. Catheter Delivery of Autologous Bone Marrow Cells in Patients with Heart Failure Due to Dilated Cardiomyopathy. Sponsor: Aastrom Biosciences, Inc.
- 2009-present Reviewer, NIH RFP NHLBI-HB-10-02: Coordinating Center to Administer the NHLBI Production Assistance for Cellular Therapies (PACT)  
Reviewer, NIH RFP NHLBI-HB-10-03: Cell Processing Facilities, Production Assistance for Cellular Therapies (PACT)
- 2009 Reviewer, NIH, RFA (OD-09-004): Characterizing Differentiated Stem Cells, Recovery Act (ARRA, RC2) at NHLBI
- 2010-present Medical Monitor: A Phase II, Double blind, Randomized, Placebo-controlled, Multi-Center Study to Assess the Efficacy and Tolerability of an Investigational Medication in Subjects with Critical Limb Ischemia. Sponsor: ViroMed, Ltd.
- 2010-present Chair, Data and Safety Monitoring Board. Feasibility Study of Autologous Concentrated Bone Marrow Nucleated Cell Therapy for Congestive Heart Failure Patients Undergoing Treatment with Coronary Artery Bypass Grafting (CABG) Surgery. Sponsor: Harvest Technologies, Inc. (BB-IDE 13801).
- 2010-present Member, Data and Safety Monitoring Board. Intramyocardial Transplantation of Bone Marrow Stem Cells for Improvement of Post-Infarct Myocardial Regeneration In Addition to CABG Surgery: A Controlled, Prospective, Randomized, Double Blinded Multicenter Trial. Sponsor: Miltenyi Biotec, GmbH.
- 2011-present Chair, Data and Safety Monitoring Board. Feasibility Study of Retrograde Delivery of Autologous Concentrated Bone Marrow Nucleated Cell Therapy for Patients Diagnosed with Congestive Heart Failure. Sponsor: Harvest Technologies, Inc.
- 2011 NIH Special Emphasis Panel/Scientific Review Group 2012/01 ZHL1 CSR-O, Cardiovascular Cell Therapy Research Network (F1), Data Coordinating Center
- 2011 Special Emphasis Panel/Scientific Review Group 2012/01 ZHL1 CSR-O, Cardiovascular Cell Therapy Research Network (F2), Clinical Centers
- 2011 Expert Panel, 2012 Mid-Term Competition, Stem Cell Network; Networks of Centres of Excellence of Canada

### **Honors**

- 1977 Upjohn Academic Achievement Award
- 1983 David Baird Award for Outstanding Teaching, Department of Medicine, Oregon Health Sciences
- 1999 Outstanding Teacher Award, Cardiology Fellowship Program, Beth Israel Medical Center
- 2009 Outstanding Teacher Award, Cardiology Fellowship Program, Columbia University Medical Center

### **C. Selected Peer-reviewed Publications**

#### **Most relevant to the current application**

1. Corti R, Badimon J, Mizsei G, Macaluso F, Lee, M, Licato P, Viles-Gonzalez J, Fuster V, Sherman W. Real time magnetic resonance guided endomyocardial local delivery. *Heart* 2005;91(3):348-53.
2. He KL, Yi GH, Sherman W, Zhou H, Zhang GP, Gu A, Kao R, Haines HB, Harvey J, Roos E, White D, Taylor DA, Wang J, Burkhoof D. Autologous skeletal myoblast transplantation improved hemodynamics and left ventricular function in chronic heart failure dogs. *J Heart Lung Transplant* 2005; 24: 1940 -1949.
3. \*Sherman W, Martens TP, Viles-Gonzalez JF, Siminiak T. Catheter-based delivery of cells to the heart. *Nat Clin Pract Cardiovasc Med*. 2006;3(suppl 1):S57-64.
4. Sherman W, Martens TP, Ketner W, Siminiak T. Percutaneous Cell Delivery Techniques: Devices and Issues. *EuroIntervention* 2007;9(Supplement B):B33-B41
5. Sherman W, Cho C, Martens TP. Burning questions in heart failure management: why do surgeons and interventional cardiologists talk of regenerative cell therapy? *Heart Fail Clin* 2007;3(2):245-52. 1)Patel AN,

- Sherman, W. Cardiac stem cell therapy from bench to bedside. *Cell Transplant* 2007;16(9):875-878
6. Sherman W. Myocyte replacement therapy: skeletal myoblasts. *Cell Transplant* 2007;16(9):971-5
  7. Hare J, Traverse J, Henry T, Dib N, Strumpf R, Schulman S, Gerstenblith G, DeMaria A, Denktas A, Gammon R, Hermiller J, Reisman M, Schaer G, Sherman W. A randomized, double-blind, placebo-controlled, dose-escalation study of intravenous adult human mesenchymal stem cells (Provacel™) following acute myocardial infarction. , *J Am Coll Cardiol* 2009
  8. Sherman W, He K, Yi G, Harvey J, Lee MJ, Haimen H, Lee P, Wang J, Burkhoff B. Myoblast-transfer in an ischemic model of heart failure: effects on rhythm stability. *Cell Transplant* 2009; 18(3): 333-41.
  9. Martens T, Godier A, Parks JJ, Wan LQ, Koeckert MS, Eng GM, Hudson BI, Sherman W, Vunjak-Novakovic G. Percutaneous Cell Delivery Into the Heart Using Hydrogels Polymerizing In Situ. *Cell Transplant* 2009; 18(3): 297-304
  10. Heng BC, Hsu SH, Cowan CM, Liu A, Tai J, Chan Y, Sherman W, Basu S. Transcatheter injection-induced changes in human bone marrow-derived mesenchymal stem cells. *Cell Transplant* 2009; 18(10): 1111-21
  11. Ozgen, N, Lau, D. H, Shlapakova, I. N, Sherman, W, Feinmark, S. J, Danilo, P., Jr, Rosen, M. R. Heart Rhythm 2010 (accepted for publication); Reactive oxygen species-induced CREB ubiquitination and proteasomal degradation determine KChIP2 transcription in ventricular pacing-induced cardiac memory
  12. Povsic, TJ, O'Connor C M, Henry R, Taussig A, Kereiakes DJ, Fortuin DF, Niederman A, Schatz R, Spencer R, Owens D, Banks M, Joseph D, Roberts R, Alexander JH, Sherman W. A Double-blind, Randomized, Controlled, Multicenter Study to Assess the Safety and Cardiovascular Effects of Skeletal Myoblast Implantation by Catheter Delivery in Patients with Chronic Heart Failure Following Myocardial Infarction. *Am Heart J*, 162(4), 654-662.
  13. Penn MS, Ellis W, Greenbaum A, Hodes Z, Gandhi S, Mendelsohn FO, Strasser D, Ting AE, Sherman W. Adventitial Delivery of an Allogeneic Bone Marrow Derived Stem Cell in AMI – Phase I Clinical Study. *Circulation Research* (online E-pub).

#### D. Research Support

03/03-10/06	Bioheart, Inc	PD/PI - Phase I, Dose Escalation, Multi Center Study to Assess the Safety and Cardiovascular Effects of Autologous Skeletal Myoblast Implantation in Congestive Heart Failure
12/08-1/10	Bioheart, Inc	PD/PI - Phase II, Double-Blind, Randomized, Controlled Multicenter Study to the Safety and Cardiovascular Effects of Autologous Skeletal Myoblasts Implantation by a Catheter Delivery System in Congestive Heart Failure
1/09-1/11	Celladon, Inc	Co-I - Calcium Up-Regulation by Percutaneous Administration of Gene Therapy in Cardiac Disease.
3/08-4/09	Abbott Vascular	PI –Dose-Ranging Study to Evaluate the Safety and Efficacy of Mesenchymal Precursor Cells delivered by Intra-myocardial Injection Catheter in Ischemia/Reperfusion Sheep Source: Abbott Vascular
11/08-Present	Athersys, Inc	co-PD/PI - A Phase I, Multicenter, Dose-Escalation Trial Evaluating the Safety of Allogeneic AMI MultiStem® in Patients with Acute Myocardial Infarction
5/08-5/11	Baxter, Inc	Site PI – A double-blind, prospective, randomized, placebo-controlled study to determine the tolerability, efficacy, safety, and dose range of intramyocardial injections of Auto-CD34+ cells for reduction of angina episodes in patients with refractory chronic myocardial ischemia
5/09-9/11	Geron, Inc	Co - PI - Cardiomyocyte Cell Transplantation in a Chronic Model of Myocardial Infarction in Immunosuppressed Domestic Swine
1/10-9/11	Juventas, Inc	Site PI - Phase I, dose escalation trial of JVS-100 delivered via endomyocardial injection in patients with ischemic heart failure

Sherman, Warren

2/12- Present	Juventas, Inc	Co – PI - Phase II Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Safety and Efficacy of a Single Dose of JVS-100 Administered by Endomyocardial Injection to Cohorts of Adults with Ischemic Heart Failure
------------------	---------------	---

# **EXHIBIT B**

**Boston  
Scientific**

**BOSTON SCIENTIFIC CORP** (BSX)

ONE BOSTON SCIENTIFIC PL  
NATICK, MA 01760-1537  
508. 650.8000  
<http://www.bostonscientific.com>

**10-Q**

**BOSTON SCIENTIFIC CORPORATION**  
Filed on 11/15/1999 - Period: 09/30/1999  
File Number 001-11083



SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

-----  
FORM 10-Q

/x/ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT  
OF 1934

For the quarterly period ended: September 30, 1999

Commission file number: 1-11083

BOSTON SCIENTIFIC CORPORATION  
(Exact name of registrant as specified in its charter)

DELAWARE  
(State or other jurisdiction  
of incorporation or organization)

04-2695240  
(I.R.S. Employer Identification No.)

One Boston Scientific Place, Natick, Massachusetts  
(Address of principal executive offices)

01760-1537  
(Zip Code)

Registrant's telephone number, including area code: (508) 650-8000

-----  
Former name, former address and former fiscal year, if changed since last  
report.

Indicate by check mark whether the registrant (1) has filed all reports required  
to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during  
the preceding 12 months (or for such shorter period that the registrant was  
required to file such reports), and (2) has been subject to such filing  
requirements for the past 90 days.

Yes ☒ [X]

No ☐ [ ]

Indicate the number of shares outstanding of each of the issuer's classes of  
common stock, as of the last practicable date.

Class	Shares Outstanding as of September 30, 1999
-----	-----
Common Stock, \$.01 Par Value	414,701,219

## ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

## RESULTS OF OPERATIONS

Net sales for the third quarter increased 20% to \$691 million as compared to \$576 million in the third quarter of 1998. The third quarter results include the operations of Schneider Worldwide (Schneider) which was acquired in the third quarter of 1998. On a pro forma basis, assuming all Schneider revenues had been included in the third quarter of 1998, net sales in the third quarter of 1999 increased 7%. Net sales for the nine months ended September 30, 1999 increased 40% to \$2,125 million as compared to \$1,517 million for the nine months ended September 30, 1998. On a pro forma basis, assuming all Schneider revenues had been included in the nine months ended September 30, 1998, net sales increased 20%.

During the third quarter of 1999, United States (U.S.) revenues increased approximately 12% to \$421 million, while international revenues increased approximately 34% to \$270 million compared to the same period in the prior year. U.S. revenues as a percentage of worldwide sales decreased from 65% in the third quarter of 1998 to 61% in the third quarter of 1999. The decrease in U.S. revenues as a percentage of worldwide sales is due primarily to the launch of a coronary stent in Japan during the first quarter of 1999 and the favorable impact of foreign currency exchange rates on translation of international revenues in the quarter as the Japanese yen strengthened versus the U.S. dollar. Without the impact of foreign currency exchange rates on translation of international revenues, worldwide sales for the third quarter increased approximately 17% compared to the same period in the prior year. Worldwide vascular and nonvascular sales increased 22% and 20%, respectively, compared to the same period in the prior year. The increases in pro forma worldwide sales and in vascular sales were primarily attributable to the Company's sales of coronary stents in the U.S. and Japan. U.S. coronary stent revenues and worldwide coronary stent revenues, primarily sales of the NIR(R) stent, were approximately \$107 million and \$156 million, respectively, during the third quarter of 1999 compared to \$82 million and \$109 million, respectively, during the third quarter of 1998.

U.S. revenues increased approximately 42% to \$1,316 million during the nine months ended September 30, 1999, while international revenues increased approximately 37% to \$809 million compared to the same period in the prior year. Without the impact of foreign currency exchange rates on translation of international revenues, worldwide sales for the nine months ended September 30, 1999 increased approximately 38% compared to the same period in the prior year. U.S. revenues as a percentage of worldwide sales increased from 61% during the nine months ended September 30, 1998 to 62% during the nine months ended September 30, 1999. Worldwide vascular and nonvascular sales increased 46% and 24%, respectively, compared to the same period in the prior year. The increases in pro forma worldwide sales and in vascular sales were primarily attributable to the Company's sales of coronary stents in the U.S. and Japan. U.S. coronary stent revenues and worldwide coronary stent revenues, primarily sales of the



NIR(R) stent, were approximately \$317 million and \$461 million, respectively for the nine months ended September 30, 1999 compared to \$82 million and \$165 million, respectively, during the same period of the prior year. Worldwide NIR(R) coronary stent sales as a percentage of worldwide sales were approximately 21% and 20% for the third quarter of 1999 and the nine months ended September 30, 1999, respectively. The NIR(R) coronary stent is supplied by Medinol Ltd. (Medinol) and unforeseen delays, stoppages or interruptions in the supply and/or mix of the NIR(R) stent could adversely affect the operating results of the Company.

On August 6, 1999, the Company announced it was voluntarily recalling from commercial distribution and use its Rotablator(R) RotaLink(TM) Advancer and RotaLink Plus(TM) rotational atherectomy systems. The original Rotablator Rotational Atherectomy Device (Rotablator), which is the product currently sold in Japan, was not affected by this recall. A program to resume the manufacture and sale of the original Rotablator was put in place and the Company began shipping product at the end of the third quarter. The Company estimates the net income that was foregone related to the recalled devices and related products to be approximately \$14 million during the third quarter of 1999.

Net income for the third quarter was \$55 million or \$0.13 per share (diluted). Third quarter results include a provision for excess inventories and purchase commitments of approximately \$62 million (\$41 million, net of tax), a provision for increased legal costs of \$22 million (\$15 million, net of tax), and a special credit of \$10 million (\$7 million, net of tax) relating primarily to previously recorded valuation reserves no longer deemed necessary. The Company reported a net loss of \$462 million or \$1.18 per share in the third quarter of 1998. The results for the third quarter of 1998 include a \$671 million (\$524 million, net of tax) charge to account for purchased research and development acquired in the \$2.1 billion cash purchase of Schneider and a provision of \$31 million (\$21 million, net of tax) for costs associated with the Company's decision to voluntarily recall the NIR ON(TM) Ranger(TM) with Sox(TM) coronary stent systems in the U.S. Net income for the nine months ended September 30, 1999 was approximately \$264 million or \$0.64 per share. This compares to a net loss of \$335 million or \$0.86 per share reported in the nine months ended September 30, 1998.

Gross profit as a percentage of net sales decreased from 64.2% in the three months ended September 30, 1998 to 59.0% in the three months ended September 30,

## SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized on November 15, 1999.

BOSTON SCIENTIFIC CORPORATION

By: /s/ Lawrence C. Best  
-----  
Name: Lawrence C. Best  
Title: Chief Financial Officer and  
Senior Vice President -  
Finance and Administration

# **EXHIBIT C**



**BOSTON SCIENTIFIC CORP** (BSX)

ONE BOSTON SCIENTIFIC PL  
NATICK, MA 01760-1537  
508. 650.8000  
<http://www.bostonscientific.com>

**10-K405**

BOSTON SCIENTIFIC CORPORATION  
Filed on 03/30/2000 - Period: 12/31/1999  
File Number 001-11083



SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

-----  
FORM 10-K  
ANNUAL REPORT PURSUANT TO  
SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 1999

Commission File No. 1-11083

-----  
BOSTON SCIENTIFIC CORPORATION  
(Exact name of Company as specified in its charter)

DELAWARE  
(State or other jurisdiction of  
incorporation or organization)

04-2695240  
(I.R.S. Employer Identification No.)

ONE BOSTON SCIENTIFIC PLACE, NATICK, MASSACHUSETTS 01760-1537  
(Address, including zip code, of principal executive offices)

(508) 650-8000  
(Company's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

COMMON STOCK, \$.01 PAR VALUE PER SHARE  
(Title of class)

Securities registered pursuant to Section 12(g) of the Act:  
NONE

-----  
Indicate by check mark whether the Company (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Company was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes    X            No  
-----

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Company's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to the Form 10-K. [X]

The aggregate market value of Common Stock held by non-affiliates (persons other than directors, executive officers, and related family entities) of the Company was approximately \$6.3 billion based on the closing price of the Common Stock on March 17, 2000.

The number of shares outstanding of the Company's Common Stock as of March 17, 2000 was 406,556,829.

#### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's 1999 Annual Report to Shareholders which is filed with the Securities and Exchange Commission (the "Commission") as an exhibit hereto and the Proxy Statement to be filed with the Securities and Exchange Commission on or about April 3, 2000 are incorporated by reference into Parts I, II and III.

established a dedicated U.S. corporate sales organization focused principally on selling to major buying groups and large integrated healthcare networks.

In 1999, the Company sold its products to over 10,000 hospitals, clinics, out-patient facilities and medical offices. The Company is not dependent on any single institution and no single institution accounted for more than 10% of the Company's net sales in 1999. Large group purchasing organizations, hospital networks and other buying groups are, however, becoming increasingly important to the Company's business. The trend toward managed care and economically motivated and more sophisticated buyers in the United States may result in continued pressure on selling prices of certain products and resulting compression on gross margins. These purchasers of medical devices also tend to limit the number of suppliers from whom they purchase medical products. There can be no assurance that these entities will continue to purchase products from the Company.

The Company markets the NIR ON(R) Ranger(TM) and NIR(R) Primo(TM) coronary stent systems which, together with other NIR(R) stent systems, represented approximately 20% of the Company's 1999 worldwide sales. These stent systems include the NIR(R) coronary stent which is developed and manufactured by Medinol Ltd., Israel, and a balloon delivery system which is developed and manufactured by the Company. The Company also distributes several other products for third parties, including RF generators, an introducer sheath and certain guidewires. None of these other products represented more than 10% of the Company's 1999 net sales. Leveraging its sales and marketing strength, the Company expects to continue to seek out new opportunities for distributing complementary products as well as new technologies. Certain of the products distributed by the Company, such as the NIR(R) stent, are very important to the Company strategically. Unforeseen delays, stoppages or interruptions in the supply and/or mix of the NIR(R) stent or certain other distributed products could adversely affect the Company's operating results.

Throughout the world, delays in product approval processes, changes in reimbursement policies and competitive pricing pressures remain unpredictable. The Company cannot predict what future economic, regulatory, reimbursement and pricing environments will exist in domestic and international markets for its healthcare products. It is possible that these environments could adversely affect the Company's product pricing and ability to sell products. The Company believes that these and other factors will continue to impact the rate at which the Company can grow, but management believes that it is well positioned to take advantage of opportunities for growth that exist in the markets it serves.

## SIGNATURE

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: March 30, 2000

BOSTON SCIENTIFIC CORPORATION

By: /s/ LAWRENCE C. BEST

-----  
Lawrence C. Best  
Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company and in the capacities and on the dates indicated.

Dated: March 30, 2000

/s/ JOHN E. ABELE

-----  
John E. Abele  
Director, Founder

Dated: March 30, 2000

/s/ LAWRENCE C. BEST

-----  
Lawrence C. Best  
Senior Vice President--Finance and  
Administration and Chief Financial Officer  
(Principal Financial and Accounting Officer)

Dated: March 30, 2000

/s/ JOSEPH A. CIFFOLILLO

-----  
Joseph A. Ciffolillo  
Director

Dated: March 30, 2000

/s/ JOEL L. FLEISHMAN

-----  
Joel L. Fleishman  
Director



Dated March 30, 2000

/s/ RAY J. GROVES

-----  
Ray J. Groves  
Director

Dated: March 30, 2000

/s/ LAWRENCE L. HORSCH

-----  
Lawrence L. Horsch  
Director

Dated: March 30, 2000

/s/ N.J. NICHOLAS, JR.

-----  
N.J. Nicholas, Jr.  
Director

Dated: March 30, 2000

/s/ PETER M. NICHOLAS

-----  
Peter M. Nicholas  
Director, Founder, Chairman of the Board

Dated March 30, 2000

/s/ JOHN E. PEPPER

-----  
John E. Pepper  
Director

Dated March 30, 2000

/s/ WARREN B. RUDMAN

-----  
Warren B. Rudman  
Director

Dated: March 30, 2000

/s/ JAMES R. TOBIN

-----  
James R. Tobin  
Director, President and  
Chief Executive Officer  
(Principal Executive Officer)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

CARDIOMEMS, INC.,

Opposer,

v.

MEDINOL LTD.,

Applicant.

In re Serial No. 85/082098

Mark: CHAMPIONIR


Opposition No. 91200436

**CERTIFICATE OF SERVICE**

I hereby certify that on this date I served the attached document via e-mail to mbaratta@kilpatricktownsend.com, as agreed by the parties, to Opposer's counsel of record:

Olivia Maria Baratta, Esq.  
Kilpatrick Townsend & Stockton LLP  
1100 Peachtree Street, NE  
Suite 2800  
Atlanta, Georgia 30309-4530  
(404) 532-6937

Dated: May 4, 2012

  
\_\_\_\_\_  
Dorothy A. Auth  
dorothy.auth@cwt.com  
John P. Halski  
john.halski@cwt.com  
Attorneys for Applicant  
Cadwalader Wickersham & Taft LLP  
One World Financial Center  
New York, NY 10281  
212-504-6000